



Substitute for form 1449B/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

## Complete if Known

Application Number	10/571,311
Filing Date	March 9, 2006
First Named Inventor	Thomas BETHKE
Art Unit	1616
Examiner Name	SOROUGH, ALI
Attorney Docket Number	27234U

Sheet 1

of 3

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	1	DIETZEL, et al., "Ciclesonide: An On-Site-Activated Steroid", Hansel TT, Barnes PJ (eds): New Drugs for Asthma, Allergy and COPD, Prog Respir Res. Basel, Karger, 2001, vol. 31, pp. 91-93.	
	2	CHAPMAN, et al., "Effects of ciclesonide versus placebo on lung function after 12 weeks of treatment in patients with asthma", Am J Respir Crit Care Med. 2002; 165: Abstract G74, 1 page.	
	3	CHAPMAN, et al., "Effects of ciclesonide versus placebo on lung function after 12 weeks of treatment in patients with asthma", Am J Respir Crit Care Med. 2002; 165: 1 page.	
	4	O'CONNOR, et al., "Management of moderate to severe bronchial asthma by ciclesonide: a 12-week trial", Am J Respir Crit Care Med. 2002; 165: Abstract G75, 1 page.	
	5	O'CONNOR, et al., "Management of moderate to severe bronchial asthma by ciclesonide: a 12-week trial", Am J Respir Crit Care Med. 2002; 165: 1 page.	
	6	PAUWELS, et al., "Effects of inhaled ciclesonide and fluticasone propionate on cortisol secretion and PC <sub>20</sub> for adenosine in asthma patients", Am J Respir Crit Care Med. 2002; 165: Abstract G84, 1 page.	
	7	O'CONNOR, et al., "Treatment of moderate to severe asthma with ciclesonide: a long-term investigation over 52 weeks", Eur Respir J. 2002; 20(suppl 38): Abstract 2579, 1 page.	
	8	ROHATAGI, et al., "Population Pharmacokinetics and Pharmacodynamics of Ciclesonide", J Clin Pharmacol, 2003; 43: pp. 365-378.	
	9	TIMMER, et al., "Repeated inhalation of the new topical steroid ciclesonide does not lead to adrenal suppression in healthy subjects", Am J Respir Crit Care Med. 2000; 161: Abstract A776, 1 page.	
	10	DROLLMANN, et al., "Ciclesonide is effective in the treatment of bronchial asthma", Eur Respir J. 2001; 18: Abstract P681, 1 page.	
	11	DROLLMANN, et al., "Ciclesonide is effective in the treatment of bronchial asthma", Eur Respir J. 2001; 18: 1 page.	

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	12	WOLTERS, et al., "Measures of systemic activity of inhaled glucocorticosteroids in children: a comparison of urine cortisol excretion and knemometry", Respiratory Medicine, vol. 89, pp. 347-349, (1995).	
	13	TAYLOR, et al., "A Dose-dependent Effect of the Novel Inhaled Corticosteroid Ciclesonide on Airway Responsiveness to Adenosine-5'-Monophosphate in Asthmatic Patients", Am J Respir Crit Care Med, vol. 160, pp. 237-243, (1999).	
	14	DEROM, et al., "Effects of inhaled ciclesonide and fluticasone propionate on cortisol secretion and airway responsiveness to adenosine 5' monophosphate in asthmatic patients", Pulmonary Pharmacology & Therapeutics, vol. 18, pp. 328-336, (2005).	
	15	GELFAND, et al., "Once-Daily Ciclesonide in Children: Efficacy and Safety in Asthma", J Pediatr, vol. 148, pp. 377-383, (2006).	
	16	POSTMA, et al., "Treatment of asthma by the inhaled corticosteroid ciclesonide given either in the morning or evening", Eur Respir J, vol. 17, pp. 1083-1088, (2001).	
	17	WEINBRENNER, A., et al., "Circadian Rhythm of Serum Cortisol after Repeated Inhalation of the New Topical Steroid Ciclesonide", The Journal of Clinical Endocrinology & Metabolism, vol. 87, no. 5, pp. 2160-2163, (2002).	
	18	AGERTOFT, et al., "Short-term lower-leg growth rate and urine cortisol excretion in children treated with ciclesonide", J Allergy Clin Immunol, vol. 115, pp. 940-945, (2005).	
	19	von BERG, et al., "Comparison of the efficacy and safety of ciclesonide 160 µg once daily vs. budesonide 400 µg once daily in children with asthma", Pediatr Allergy Immunol, vol. 18, pp. 391-400, (2007).	
	20	SKONER, et al., "Assessment of the Long-term Safety of Inhaled Ciclesonide on Growth in Children With Asthma", Pediatrics, vol. 121, no. 1, pp. e1-e14, (2008).	
	21	LIPWORTH, et al., "Effect of ciclesonide and fluticasone on hypothalamic-pituitary-adrenal axis function in adults with mild-to-moderate persistent asthma", Ann Allergy Asthma Immunol, vol. 94, pp. 465-472, (2005).	

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	22	BOULET, et al., "A randomized study comparing ciclesonide and fluticasone propionate in patients with moderate persistent asthma", Respiratory Medicine, vol. 101, pp. 1677-1686, (2007), Elsevier.	
	23	PEDERSEN, et al., "A Comparative Study of Inhaled Ciclesonide 160 µg/day and Fluticasone Propionate 176 µg/day in Children With Asthma", Pediatric Pulmonology, vol. 41, pp. 954-961, (2006), Wiley-Liss, Inc.	
	24	LEE, et al., "Airway and Systemic Effects of Hydrofluoroalkane Formulations of High-Dose Ciclesonide and Fluticasone in Moderate Persistent Asthma", Chest, vol. 127, pp. 851-860, (2005).	
	25	SZEFLER, et al., "Ciclesonide, a Novel Inhaled Steroid, Does Not Affect Hypothalamic-Pituitary-Adrenal Axis Function in Patients With Moderate-to-Severe Persistent Asthma", Chest, vol. 128, pp. 1104-1114, (2005).	
	26	AGERTOFT, et al., "Lower leg growth rates in children with asthma during treatment with ciclesonide and fluticasone propionate", Pediatr Allergy Immunol, pp. 1-7 (2009).	

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